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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/636,079	08/06/2003	Janet K. Yamamoto	UF-152FWCD2	1433
23557	7590	02/08/2005	EXAMINER	
SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950			CHEN, STACY BROWN	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 02/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/636,079

Applicant(s)

YAMAMOTO, JANET K.

Examiner

Stacy B Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-97 is/are pending in the application.
- 4a) Of the above claim(s) 64-97 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 31-43 and 50-63 is/are allowed allowable. *SBE 1/27/2005*
- 6) ☒ Claim(s) 18-30 and 44-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

1. Applicant's amendment and response filed November 26, 2004 is acknowledged and entered. Claims 31-97 are pending. Claims 64-97 remain withdrawn from consideration, being drawn to non-elected inventions. Claims 31-63 are under examination.

Response to Amendment

2. The following objection and rejections are withdrawn in view of Applicant's response:
- The objection of claim 18 is withdrawn in view of Applicant's amendment spelling out the acronym, "FIV".
 - The rejection of claims 18-63 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,544,528, is withdrawn in view of the acceptance of the terminal disclaimer filed November 26, 2004. The rejection of claims 18-30 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-38 of U.S. Patent No. 6,605,282, is withdrawn in view of the acceptance of the terminal disclaimer filed November 26, 2004.
 - The rejection of claims 18-23, 27 and 28 under 35 U.S.C. 102(b) as being anticipated by Yamamoto *et al.* (*Intervirology*, 1991, 32:361-375) is withdrawn in view of Applicant's persuasive arguments. The rejection of claim 24 under 35 U.S.C. 103(a) as being unpatentable over Yamamoto as applied to claims 18-23 above, and further in view of Francis (WO 94/06471), is withdrawn in view of Applicant's persuasive arguments. The cell line taught by Yamamoto *et al.* is dependent on FIV infection for its IL-2

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independence. The cell lines instantly claimed do not require FIV infection for IL-2 independence.

- The rejection of claims 18-63 under 35 U.S.C. 112, first paragraph, for only being enabling for a vaccine for domestic cats comprising FIV inactivated whole virus or inactivated FIV-infected cells comprising subtypes A and D, is withdrawn in view of Applicant's persuasive arguments.
 - Regarding the issue surrounding domestic cats, Applicant points out that only animals susceptible to FIV infection are encompassed by the claims (see claim 31 which includes the limitation, "susceptible to infection by FIV").
 - Regarding the Office's interpretation of the claim language to encompass a single immunogen subtype vaccine, Applicant argues that claim 31 is drawn to a vaccine composition comprising an immunogen or immunogens from or comprising at least two different FIV subtypes. In view of this argument, the claims are now understood to mean that both the immunogen and the immunogens comprise at least two different subtypes. In view of this interpretation of the claims, the claims are enabled for a vaccine against two or more subtypes comprising at least two immunogen(s) comprising at least two different subtypes. Evidence for this enablement is found in Yamamoto *et al.* (*AIDScience*, vol. 2, no. 8 (2002) page 3, last two paragraphs and Table 2) which discloses that inactivated whole viruses and inactivated FIV-infected cells comprising FIV subtypes A and D isolated from two long-term nonprogressor cats () provide protection against FIV subtypes A, B and D.

- Regarding the enablement of a viral vector vaccine, the Office has considered that none of the claims specifically recite this embodiment although it is encompassed by claim 31 and dependent claims that do not specify the types of immunogens to be used in the vaccine. Applicant points to Tellier *et al.* (*AIDS*, 1998, 12:11-18) to demonstrate that canarypox-FIV vaccines induce protection. Tellier's ALVAC-FIV vector vaccine encoded gag, pol and env; the vaccine protected cats against homologous challenge. A conflicting interpretation of Tellier's results is shown in Yamamoto *et al.* (*AIDScience*) which discloses that vector vaccines (feline herpesvirus, adenovirus and canarypox virus vectored FIV genes) provided no protection (see Table 2). Regardless of these seemingly conflicting results, claim 31 broadly encompasses several other enabled embodiments besides vector vaccines, and therefore the rejection is withdrawn.

Response to Arguments

3. The rejection of claims 18-30 and 44-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained for reasons of record.

Applicant's arguments have been carefully considered but fail to persuade. The claims are generally drawn to IL-2 independent feline-derived T cells. The Office rejected the claims on the basis that the identity of the cells was not known and therefore requires a deposit.

Applicant's substantive argument is primarily directed to the assertion that the identifying characteristics of the deposited cell lines can be readily determined. For example, the deposited cell line can be obtained from the ATCC® and a cell surface antigen expression profile can be

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determined to identify the identifying characteristics of the cell line. In response, the identifying characteristics of the cell line may be shared with other cell lines, or they may be unique to that particular cell line. The specification does not show possession of the identifying characteristics such that one of skill in the art would be able to obtain the claimed feline-derived T cells. The identifying characteristics of the derived cells are the patentability-determining features of the cells. Without knowing what those are, Applicant has not demonstrated possession of the derived cells. Therefore, the rejection is maintained.

4. The rejection of claims 18-30 and 44-49 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is maintained over the following grounds for reasons of record. (Applicant's arguments regarding the meaning of "partial FIV" are persuasive. Applicant's amendment that deletes the term "derived" in claims 31 and 64.)

- Claims 18-30 recite "feline-derived". Applicant argues that the term "feline-derived" indicates that the cells are feline cells. In response, Applicant has not defined what aspect of the feline cell is retained after derivation. Since the feline-derived cell is a feline cell, suggested language is "feline T cell". If the term "derived" is used only to imply a method of making that does not structurally change the cell, then the term is not necessary for patentability.
- Claims 44-49 recite, "identifying characteristics". Applicant argues that the ordinarily skilled artisan would understand that identifying characteristics of a cell are those characteristics that can be used to distinguish the cell from other types of cells or cell

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lines. In response, the specification does not define what the identifying characteristics are. Simply saying that the identifying characteristics are those that are distinguishing from other cells is not defining the actual characteristics. If the characteristics are antigens, then the claims should point out what antigens are distinguishing over other cells.

5. Claims 27 and 28 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting over claims 19-63 of co-pending application number 10/408,701. Applicant argues that the claims are not obvious over the co-pending claims. However, this provisional rejection is maintained for reasons of record.

Conclusion

6. Claims 18-30 and 44-49 remain rejected. Claims 31-43 and 50-63 are free of the prior art of record. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James C. Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

SBC

Stacy B. Chen
January 27, 2005

James C. Housel
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
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2/7/05